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Maintaining Ethical integrity during Clinical Research in Midwifery

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Maintaining Ethical integrity during Clinical Research in Midwifery

Abstract

This paper explores the issues related to maintaining ethical integrity during clinical research in midwifery. An overview of what are ethical principles is provided within the discussion. Particular attention is paid to some of the ethical issues that may face researchers and clinicians such as researching with vulnerable groups in midwifery like neonates, and obtaining ethical consent. Guidelines are proposed to aid both researchers and clinicians to know when research is being conducted in an ethical manner.

Key Words

Ethics, midwifery, clinical research, data collection, consent, advocacy.

Introduction

Research in midwifery is growing in response to public accountability[1]. Evidence based practice has become a major guiding principle to deliver care. Such a principle encourages midwives and other health care professionals to clinically practice using the best available research evidence, rather than traditional and routine practices[1].

Incorporating research evidence into practice has lead to core curriculum changes to midwifery education to include research skills. Further, research conducted in the clinical areas of midwifery means that many midwives are encountering or involved in research activities, especially in data collection. As midwifery research can include

many vulnerable groups such as neonates, it is important that midwives involved in clinical research are aware of ethical principles and what strategies can be used to ensure ethical principles are maintained throughout the research process.

Ethical principles have derived over time with one of the most influential situations being the discovery of cruel and brutal experiments using Jewish prisoners of war in the Second World War. Most countries, including Australia have now developed codes of ethical conduct guidelines to undertake research appropriately[2]. The National Health and Medical Council Act in 1992 was a significant Commonwealth Parliament initiative in Australia to create a national body, the National Health and Medical Research Council (NHMRC), which facilitates public health research. Part of the role of the NHMRC is to recommend ethical principles[2].

Today researchers are obliged to protect any potential or actual research participant. There is a structured process for obtaining ethical approval prior to the commencement of research. Human Ethics Committees have been established to examine research proposals to facilitate the implementation of ethically sound research.

Ethical Principles

There are a number of ethical principles useful to guide midwives engaged in research, which include the key principles of respect for autonomy or the right to be protected[3], non-maleficence, beneficence, research integrity, and justice[1,4,5,6].

Beneficence and Non-maleficence

Beneficence is the moral obligation to promote good, whilst non-maleficence is to prevent or remove harm[5,6,7,8]. Ethical research is about promoting the advancement of knowledge (maximum benefit) through minimal consequences to those that are the research participants[6]. Neuman[9] (2003, p. 119) summarises this principle by saying, "never cause unnecessary or irreversible harm to subjects … and never unnecessarily humiliate, degrade, or release harmful information about specific individuals that was collected for research purposes". Maintaining beneficence and avoiding harm is the researcher/s obligation[3].

One example has been presented by Manias and Street[10] (2000) where observational field notes were used to record relationships between nurse-nurse and nurse-doctor in a hospital setting. One nurse manager had requested to examine these notes, hoping that this would help her own management of a particular staff member. Had these researchers allowed this manager to view these notes the staff member may have been at risk, as information was being shared for a different purpose and may have been taken out of context and therefore, misinterpreted. In this case the notes were not shared with the manager and it was argued that the research participants had consented to the project on the condition that their identity remained anonymous.

The protecting of private information includes:

- Details of the participant's name & age
- Contact details
- Other information that could identify a person, such as position in employment

Research Integrity

There are many risks to the research participants but these risks can be reduced by ensuring research is conducted by knowledgeable and capable researchers [1,6,7]. The guidelines from the NHMRC[2] (1999) under the section of 'Research Merit and Safety', point 1.15 state that 'research must be conducted or supervised only by persons or teams with experience, qualifications and competence appropriate to the research[2].

The increased clinical research in midwifery is encouraging, but it is worth being cautious and critical, and if any researcher has insufficient knowledge or experience about research, than they should access supervision to ensure that research is conducted in an appropriate manner[1]. Ethical research conducted by knowledgeable researchers will maintain non-maleficence during the research process[9].

Justice

Ethics includes the notion of being just. Justice is about *who* should receive benefits and *who* bears the research burdens[2]. No one group can be disadvantaged, for example, mothers who are classified as private patients in a maternity ward should not be the only ones receiving the therapeutic benefits, whilst mothers classified as public patients be the only ones recruited for the control group where less benefit is expected. All participants should be treated fairly and randomised allocation to

treatment and control groups is one strategy useful to ensure just and moral involvement in the research[1].

However, whether a research project is just and morally acceptable is a complex issue. According to Kessel (1998)[5] there are three different theories that define when an action is morally acceptable. These three theories are defined as an outcome- based theory (goal-based), a principle based theory, and a rights based theory. With an outcome based theory the research is morally correct if the outcome is seen as 'good'(typically by science or society)[1]. Using a principle based theory, even if there is a good outcome the research project must be achieved using certain principles, such as not lying. A rights based theory argues that a research project is just if the rights of an individual are considered. This theory argues that a good outcome for the community is not always appropriate if the rights of an individual research participant are not considered.

Scenario 1: A baby is stillborn, which is unexpected. An autopsy is ordered. Following the autopsy, research is undertaken on the dead body without consent from the parents.

Critical Reflection 1: Research examining the dead body of the neonate could provide valuable knowledge that may lead to prevention of some future stillbirths. However, the rights of individuals (the parents) have been overlooked and therefore, this scenario is unethical and morally incorrect as the researchers have not been honest with the parents, as to their intentions[11].

Kessel [5] (1998) believes that the researcher/s should consider all three of the moral theories and suggests that each approach to moral ethics can provide a researcher/s or clinician/s with valuable inquiry to ensure that the research project is morally ethical. For example, by using the outcome based theory useful questions can ensure an ethically sound research project such as, will the research findings be useful to midwifery and is the research designed to achieve its goal[1,2]? If the research design is not appropriately identified then it is possible that the research question will not be answered and the objectives of the research project will not be met[6]. This can be considered immoral as the research may be meaningless and in itself unnecessary, and therefore unethical. Using a principle based theory it is possible to question how the research participants will be treated and to evaluate if the risk of being involved in the research project is greater than an acceptable minimal level[2]. Finally, the rights based theory could question whether the individual will be respected, be informed and if his/her identity will be kept confidential[1].

An additional fundamental principle of justice is about advocacy. Some potential and actual research participant groups are vulnerable populations and therefore require researchers and midwives to act as advocates if there is a possibility of exploitation. It is also argued that researchers should be accountable throughout the research process, particularly for clinical research that involves these vulnerable populations [12]. There are many vulnerable groups but the following are commonly identified in this way and are classified as [7]:

- people from low socio-economic status,
- adolescent mothers, single mothers,
- women living with mental illness,

- and ethnic minority groups, particularly when these women are unable to speak the dominant language, such as English.

Scenario 2: Research is being conducted to examine some of the issues related to having postnatal depression. As the researcher, you are concerned that encouraging women to talk about these experiences may be distressing. You want to be prepared and to conduct this research project in an ethical manner.

Critical Reflection 2: Questions in such sensitive areas can become deeply searching from a personal perspective of the research participant and can release a range of disturbing emotional responses such as shame, guilt and fear. It is important prior to commencing the research to consider the level of risk of possible distressing emotional reactions to answering questions or telling personal stories about the experiences and to plan appropriate support following the research such as referral to counselling. However, such research can be justified, not just because it adds to knowledge but from an ethical perspective of benefit for the research participant. The research participant may experience cathartic response from being able to share such sensitive content to a non-judgemental and interested person (the researcher) who is obliged to keep the person's identity confidential[13,14].

Respect for Autonomy

Autonomy refers to the right to self govern. Through self governance people make decisions[8]. The application of the principle of respect for autonomy in research means that research participants are able to[2, 6]:

- agree or disagree to participate in research,
- withdraw at any time of the research
- refuse to answer a particular question or section of questions (modify the level of participation)

Scenario 3: Ms Elf is a research participant in a study about domestic violence. She confides in you as the midwife caring for her that she was having some trouble finishing the questions on the questionnaire, as she would prefer not to disclose some information.

Critical Reflection 3: No research participant is obliged to disclose any information that they do not wish to share. Standard ethical approval includes the right for any participant not to answer a particular question or to withdraw at any time during the research without repercussions[2].

The other group that is relevant to autonomy is those that are unable to make decisions for themselves, for example, neonates, or who have diminished capacity to be autonomous, such as women with psychosis. These vulnerable groups have the right to be protected[8]. For example, the NHMRC[2] principles provide clear guidelines for involving neonates or premature infants in research. The research can only be conducted if the research question is significant for health and wellbeing of neonates and that other research using older subjects is unable to answer the research question. At all times the research should consider the safety and well being of the research participants. This offers difficulty for those infants in neonatal intensive care as very little additional interventions imposed could jeopardise the infant's well being[2].

Consent

A major potential ethical issue in clinical research is related to informed consent[1, 2]. The researcher should inform potential research participants about the study, including things like:

- purpose of the study
- level and degree of involvement in the research project,
- any benefits or expected consequences of being involved in the study (risk)[15],
- how the information will be collected, stored and disseminated,
- confidentiality.

Participation must be voluntary and not coerced [5, 7]. When obtaining consent to participate in research the information to potential research participants should be phrased in a way that can be understood by these people [1,5,8]. Plain language statements and verbal explanations that contain appropriate language such as being pitched at a correct educational or development level or is culturally appropriate will ensure that people can understand and will aid potential research participants in reaching an informed decision about participation in a research project[1, 6]. Additionally, providing plenty of time to read and ask questions about the research and consent forms is an essential strategy to ensuring ethical recruitment of research participants[1].

However, in some research designs it is inappropriate for the integrity of the research, to provide all information to potential research participants[1, 2, 3, 16] . An example is when human behaviour would change if the participants where aware of being

watched, such as when research is undertaken to examine the hand washing practices of midwives. In this case guidelines have been proposed to ensure the research is conducted in a sound manner. When uninformed participation is involved in a research project the researcher/s must confidently argue to an Human Ethics Committee that there will be no harmful affect to the research participants because they have not been told this information[17.] . The NHMRC[2] also suggests that participants should be informed immediately after the collection of data and have the choice to withdraw any or all of the data if they choose to do so.

There are many issues around the obtaining and sustaining of consent during research that relate to the health care area. Conducting research at any time of delivering health care could be seen as potentially intrusive. However, certain circumstances during the childbearing period may make research participants more vulnerable. For example, anxiety or certain medication like opoids (morphine) can interfere with the ability to make decisions, process or to retain information[7].

Scenario 4: Mrs Olger is post caesarean and as the midwife caring for her you decide to check on her wound. On entering Mrs Olger's room you find her reading the questionnaire that has been left for her to fill out as a participant of a research project. The research project is about experiencing an unexpected emergency caesarean. She makes a comment to you that she remembers agreeing to be a participant but that she cannot recall anything about project. She tells you that a researcher came and spoke to her about this research project. She signed a consent form shortly after returning from the recovery ward to the postnatal ward. She had been given an intramuscular injection of Morphine fifteen minutes prior to this event.

Critical Reflection 4: In this scenario it is possible that the woman has not retained or processed the information in a logical manner due to the medication or she may have been experiencing anxiety. It is appropriate to refer this research participant back to the researcher for additional consent prior to this woman continuing with this research.

Certain groups are classified as more vulnerable than others as they are unable to consent to research. This includes the fetus and the neonate. In this case, it is recommended that parents/guardian/s or alternatively, others by law will need to consent for neonates to be included in a research project[2].

Whilst there is the concern about the vulnerability of particular groups like pregnant women and neonates, there is also a great need for further research in these areas as studies involving adults do not provide appropriate and accurate information for these groups and for children[18, 19, 20]. Therefore, careful consideration is required to ensure that further knowledge and understanding is developed, whilst these vulnerable groups are ethically protected against harm. For example, to maintain an ethically sound research project, consent should be obtained from the mother and where possible the father before research involving a fetus commences. This includes any research that involves fetal tissue, membranes, placental, umbilical cord and amniotic fluid[5]. The guidelines set out by the NHMRC suggested that a clinician has an important part to play in determining the suitability of approaching a mother for consent to research involving the fetus or associated fetal products, rather than a researcher[21].

Complex Ethical Issues Found in Midwifery Research

There are a number of complex ethical issues that may be encountered in midwifery research. Some examples will be mentioned here merely to raise the issue that researcher/s and clinician/s need to be aware of this complexity. Roberts[6] (2002, p. 113) raised the issue that it is 'unethical to administer drugs to or carry out any procedure on the mother to find out any harmful effects on the fetus, even if abortion is anticipated'. Additionally, there is an expectation that respect will also be awarded to a pre-viable fetus, that is a fetus that has not reached the age of 20 weeks gestation or who weighs 400gms or less. This respect is clearly outlined in the NHMRC guidelines[21] and it is recommended that a dead fetus should be removed from the clinical area before any research is conducted. This ensures that clinical decision-making is separated from research decision-making in order to prevent any conflict of interest.

More recently, the issue of randomised clinical trials have been raised as a concern from an ethical perspective[1, 2,22]. The issue is that harm may occur to those who are in the control group if treatment is withheld. Therefore, during a clinical trial, the researcher/s must ensure that all participants, regardless of whether they are in the intervention group or the control still receive appropriate care[22]. One appropriate strategy is for those participants in the control group to receive the usual care that would be typically given, whilst the intervention group receive the different but proposed as an alternative treatment/care that is being tested in the research project[1].

Looking Closely at the Role of the Clinical Midwife associated with Research

The clinical midwife can play an important part in the research process to assist their clients during research. The typical role of advocacy continues to be relevant. Being an advocate for a research participant can include:

- acting on that person's behalf to request further information from the researchers prior to consenting,
- acting on that person's behalf to request further information from the researchers during the research project[7],
- and being present during the time of consent.

Midwives caring for clients may be involved in research as a witness to a research participant's signature on the research consent form. Like any other document this is merely the acknowledgement that the person cited was the person who signed the consent form. However, it is not the role of clinical midwives (bedside practitioners) who are not working as researchers to provide a description of the study in order to obtain informed consent[7]. Rather, this is the role of the researcher, in particular the chief investigator or project manager.

Scenario 1: As the midwife caring for Ms Wills that evening you are asked by her if you would witness her signing a consent form to agree to be research participant. You agree and then she asks if you could tell her why the researchers need to take blood from her for this research.

Critical Reflection: In this scenario it is possible that the woman is about to consent but not to give informed consent. If a potential research participant does not understand her involvement in the research and requests further information it is most appropriate to refer this potential participant back to the researcher for further information prior to consent. Ethically, the emphasis is placed on the notion that consent is *informed.*

Conclusions

This paper has explored the issues related to maintaining ethical integrity during clinical research in midwifery. It was cautioned that all researchers should question their knowledge and ability to conduct research in order to undertake a research project in an ethical manner. It was suggested that supervision should be sought to ensure research integrity for inexperienced researchers. Following an overview of commonly practiced ethical principles, a number of issues where raised that researchers and clinical midwives may encounter when associated with clinical research. There is the need to ensure that clinical midwives, particularly those who are involved with collecting data are aware of the scope and alternatively, the limitations of the role of data collection. Some of these issues were related to informed consent and being an advocate for a potential or current research participant. Finally, throughout the paper actual scenarios were provided for examples of typical ethical issues that arise during clinical research.

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